

# Practical hints and tips when notifying



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# Aims for Part 2 of the workshop

- background on notifications
- the assessors and what they do
- hints and tips when submitting CU2s
- CU2 exercise
- discussion and feedback

# Purpose of notifications

- statutory requirement
- CU2 provides a structure to present essential information
- gives the regulator a summary of the proposed work, hazards and controls
- may help users identify deficiencies in the risk assessment



# Duties on the Competent Authority

- legal obligations on the CA laid out in the regulations (23-29)
- CA has responsibilities to *assess the information to ensure that, among other things, the risk assessment is sufficient and the classification of the work is appropriate to protect human health and the environment*
- consider the assessors when presenting the information

# What prompts more questions?



- poorly defined – too broad/ narrow
- insufficient/ poor quality information
- lack of information on risks to the environment
- lack of detail on waste inactivation/ validation
- derogations not justified/ alternatives not explained, or incorrect
- requests for non-disclosure not justified
- empty boxes

# Over to you....

complete a CU2 for the work discussed earlier

- decide on what to include/ not to include in boxes
- types of information to include rather than specific (but can refer to earlier example RA)
- approx. 30 mins

discussion and questions



cu2.pdf



# Take home messages



- Avoid cryptic or orphan information and references
- Cover environmental risk, even if there is none
- Describe and assess animal work fully
- Justify why information should not be included on the public register
- Don't put non-disclosable information in the areas marked 'public register'
- Request derogations needed and justify why they are reasonable
- Present your CU2 or Sig Change letter in a way that ***guides the HSE/ Defra reviewers*** through the key safety aspects of the work



# Any last questions?







# Connected programmes

- brigade notifications together
  - avoids repeated submissions
- what is the connection?
  - clear common research objective
  - common technique or approach e.g. lentiviral vectors
  - similar exposure risks requiring similar containment and control
  - routine work using similar defined procedures



# Connected programme of work



- give it a title that reflects the purpose of the programme
- provide more than 1 risk assessment covering work included in the CPW
- include reasoning as to why the GMSC concluded it is covered by a CPW
- outline what is *and what isn't* covered by the CPW
- don't be greedy!

# Significant change

- different organisms/ strains with different inherent characteristics
- different genetic inserts which alter inherent characteristics of the final GMO
- nature of the activity (e.g. *in vitro* – *in vivo*)
- new information on consequences of exposure



changes to containment and control measures or  
changes to anything that alters the basis upon which  
HSE gave clearance/consent

# tips on notifying significant changes



- duty to inform HSE of any changes that affect the risks associated with activities for which clearance/ consent given
- changes should be incorporated into the risk assessment
- risk assessment should be reviewed by GMSC
- revised risk assessment should be sent to the HSE, along with a letter setting out the significant changes